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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/512,568	02/24/00	HEIN M	TSRI-184.2Co

HM12/1213

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EXAMINER	
BUI,P	
ART UNIT	**PAPER NUMBER**
1638	4

DATE MAILED: 12/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/512,568	Hein et al.
Examiner	**Group Art Unit**
Phuong Bui	1638

☒ Responsive to communication(s) filed on *Feb 24, 2000*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *21-64* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *21-64* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *3*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The Office acknowledges the receipt of preliminary Amendment A, Paper No. 2, filed February 24, 2000. Claims 21-64 are pending and are examined in the instant application.

Specification

2. Applicant is required to update the status (pending, allowed, etc.) of all parent priority applications in the specification.

Information Disclosure Statement

3. An initialed and dated copy of Applicant's IDS form 1449, Paper No. 3, filed March 24, 2000 is attached to the instant Office action. The During reference is considered only to the extent of Applicant's submitted English translation, which does not appear to be a complete translation of its German counterpart.

Drawings

4. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Double patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 21-64 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-30 and 36-37 of copending Application No. 09/199534. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application allows for the inclusion of a leader sequence, which was well known in the art, as evidenced by the new prior art rejections below, also see von Heijne (J. Mol. Biol., 1985, Vol. 184, p. 99-105 (Applicant's IDS)). Furthermore, it would have been obvious to utilize the methods set forth in claims 36-37 of the 09/199534 application to make the claimed product since the method simply introduced the nucleotides containing the gene of interest into the claimed transgenic plant, and thus would not be patentably distinct from the transgenic plant.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 21-64 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21 and 32-78 of copending Application No. 09/200657. Although the conflicting claims are not identical, they are not patentably distinct from each other because immunoglobulins and antibodies are the prototypic and main species of multimeric proteins.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 21-64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-12 of U.S. Patent No. 5,959,177. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the genus-species relationship, i.e., the species renders the genus obvious. The scope of the claims of the instant application (genus) fully encompasses the patented claims (species). The heavy chain and/or light chain of the antibody species renders obvious the immunoglobulin and multimeric protein genus. Further, Fab, Fab', F(ab)2, Fv and J chain were well known antibody components. Thus, the claims of the instant application is rendered obvious by the patented claims.

9. Claims 21-64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 5,202,422. Although the conflicting claims are not identical, they are not patentably distinct from each other because the multimeric proteins and immunoglobulins are the prototypic and main species of glycopolypeptide multimeric proteins which are used to induce passive immunity (Abstract and col. 2, ln. 62-64 of the patent). The method of making holds little weight in the patentability of the product if the products are identical. Again, antibody components were well known in the prior art (see above rejection).

10. Claims 21-64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5,639,947. Although the

conflicting claims are not identical, they are not patentably distinct from each other because the immunoglobulin species of the patent renders obvious the multimeric protein genus of the instant application.

Claim Rejections - 35 USC § 112, second paragraph

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 30, 41, 52 and 61-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 30 and 52, it is unclear what is joined by hydrogen boding: the multimeric proteins or components within a multimeric protein.

Further, claim 21 is directed to a multicellular plant. Claim 41 indicates that the plant is an alga. Since algae can be both unicellular and multicellular, it is presumed that claim 41 excludes unicellular alga. If not, clarification is required.

In claims 61-63, it is unclear what is being retained in the "derived" product. It is suggested that "derived" be amended to "wherein said plant cell is".

Clarification and/or correction are required.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

14. Claims 21, 22, 24-26, 29-39, 42-44, 46-48, 51-61 and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by During (Dissertation, July 9, 1988, University of Koln, FRG, English translation (Applicant's IDS)). During teaches a transgenic tobacco plant comprising cells which contain and express nucleotide sequences encoding an anti-NP-IgM antibody, which is a heteromultimeric protein. The antibody was glycosylated (p. 4 of English translation) and appears to be free of sialic acid residues. The antibody would inherently possess one or more disulfide bonds, hydrogen bonding, Fab, Fab', F(ab')2, Fv, and J chain, and would contain a paratope. Accordingly, During anticipated the claimed invention.

15. Claims 21-27, 29-40, 42-49, 51-62 and 64 are rejected under 35 U.S.C. 102(e) as being anticipated by Goodman (US Pat. No. 4956282 (Applicant's IDS)). Goodman teaches transformation of monocots and dicots by introducing a vector containing nucleotide sequences encoding interferon (homomultimer), enzymes and immunoglobulin heavy and light chains for expressing immunoglobulins (heteromultimer) (col. 3, ln. 20-30). The antibody would inherently possess the Fab, Fab', F(ab)2, Fv and J chain regions, since these are all antibody components. The antibody would inherently bind a predetermined antigen and possess a paratope. The antibody of Goodman appears to be glycosylated (since Goodman desires retention of its

biological activity) and free of sialic acid. Accordingly, absent of evidence to the contrary, Goodman anticipated the claimed invention.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claims 21-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over During (Dissertation, July 9, 1988, University of Koln, FRG, English translation (Applicant's IDS)), as applied to claims 21, 22, 24-26, 29-39, 42-44, 46-48, 51-61 and 64 above, and further in view of Applicant's admitted prior art. The teachings of During have been discussed above. While During does not teach transformation of monocots or algae, transformation of these would have been well within the means of one of ordinary skill in the art without any surprising or unexpected results. It is noted that the examples are directed to transformation of a tobacco and the claims encompass monocots, algae and dicots. Also, while the antibody of During is a heteromultimeric protein (at least two different subunits), it would have been well within the means of one of ordinary skill in the art to make any known homomultimeric protein (at least two of the same subunits) based upon the teachings of During for making a heteromultimeric protein with a reasonable expectation of success, since the complexity and novelty of the invention lie with the multimeric protein property, rather than with the subunits per se. Again, it should be noted that

the examples in Applicant's disclosure are directed to making an IgA antibody (heteromultimeric protein) and the claims encompass both heteromultimeric and homomultimeric proteins. The multimeric proteins which can expressed in plants based upon the teachings of During may or may not have enzymatic activity, since multimeric enzymes were notoriously well known in the prior art (p. 30). Further, while the antibody of During does not have catalytic activity (abzyme), it would have been obvious to transform plants using the method of During to express another desired antibody, such as abzymes of the prior art (specification, p. 30), without any surprising or unexpected results. Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to generate the claimed invention based upon the teachings of During with a reasonable expectation of success.

18. Claims 21-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman (US Pat. No. 4956282 (Applicant's IDS)), as applied to claims 21-27, 29-40, 42-49, 51-62 and 64 above, and further in view of Applicant's admitted prior art. The teachings of Goodman have been discussed above. While Goodman does not teach transformation of algae, such transformation would have been well within the means of one of ordinary skill in the art without any surprising or unexpected results. It is noted that the examples are directed to transformation of a tobacco and the claims encompass monocots, algae and dicots. Also, while the antibody of Goodman generically does not have catalytic activity (abzyme), it would have been obvious to transform plants using the method of Goodman to express another desired antibody, such as abzymes of the prior art (specification, p. 30), without any surprising or unexpected results. It

should also be noted that the antibody exemplified in the instant specification does not have enzymatic activity (abzyme). Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to transform monocots, algae or dicots, as well as express another antibody including abzymes using the method of Goodman with a reasonable expectation of success.

Remarks

19. No claim is allowed.

20. Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Bui whose telephone number is (703) 305-1996. The Examiner can normally be reached Monday-Friday from 6:30 AM - 4:00 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Phuong Bui
Primary Examiner
Group Art Unit 1638
November 20, 2000

Phuong Bui
PHUONG T. BUI
PRIMARY EXAMINER